IT'IS FOUNDATION

*Foundation for Research on Information Technologies in Society*

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# Comments To ET Docket No. 03-137 of IT'IS Foundation

## Summary


- We respectfully object to the 100mW exclusion for scientific, technical and engineering reasons. The rationale provided (in Paragraph 18 and elsewhere) is faulty.
- We object to the proposal for using spatial averaging of incident field strength to determine compliance with spatial peak SAR limits.
- We question the decision to allow the demonstration of compliance of implanted medical devices using only FDTD analysis. Measurements should also be required.
- We also request additional rationale for the minimum distances for the exclusion of certain devices presented in Table 1


**Document**

**Before the**
**Federal Communications Commission**
**Washington, D.C. 20554**

| | |
|---|---|
| In the Matter of | ) |
| | ) |
| Proposed Changes in the Commission's Rules | ) |
| Regarding Human Exposure to | ) ET Docket No. 03-137 |
| Radiofrequency Electromagnetic Fields | ) |

**NOTICE OF PROPOSED RULE MAKING**
**Adopted:** June 12, 2003 **Released:** June 26, 2003

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## Detailed Comments

### Background

The Foundation for Research on Information Technologies in Society (IT'IS) was founded on November 17th, 1999 through the initiative and support of the Swiss Federal Institute of Technology in Zurich (ETH), the global wireless communications industry and several governmental agencies.

Today the IT'IS Foundation is the largest research organization in RF exposure assessment and dosimetry (5 post-Doc and 10 PhD students). IT'IS has provided most of the scientific basis as well as the procedures for testing compliance for RF devices operating close to the body. IT'IS actively participates in the standardization process of IEEE, IEC as well as Asian committees. IT'IS also consults with industry with respect to optimization of devices.

IT'IS has developed the most advanced measurement and simulation technology for dosimetry available today. The research results have been commercialized by several companies such as SPEAG (DASY4, SEMCAD), SARTEST, etc.

The number of publications of IT'IS in this field exceeds 200. For more detail see http://www.itis.ethz.ch.

### Objection No.1: 100mW Exclusion Can Not Be Justified

In Paragraph 18, the FCC proposes to require SAR evaluations of consumer devices that are designed for use within 20 cm of the body, *only* if the maximum peak output power of the device exceeds 100mW. SAR evaluations are not required for devices below 100mW.

This statement caught us by surprise since it is widely known that this exemption is in sharp contradiction with the limit of spatial peak SAR of 1.6W/kg averaged over 1g. This is evident from the following examples:

1) Application of the SAR approximation for devices operated close to the body [1], [2]. Examples are given below:
   a) SAR_1g = 15 W/kg (Pin = 100mW, f=2.45 GHz, d=5mm, Z_fp=50Ohm)
   b) SAR_1g = 75 W/kg (Pin = 100mW, f=2.45 GHz, d=5mm, Z_fp=10Ohm)
   c) SAR_1g = 33 W/kg (Pin = 100mW, f=5.8 GHz, d=5mm, Z_fp=50Ohm)
2) Scalling of the measured spatial peak SAR of dipoles given in Table 8-1 of IEE1528 [3] or Table X.4 of IEC Draft 62209 - Part 2 [5] to 100mW:
   a) SAR_1g = 4 W/kg (Pin = 100mW, f=1.9 GHz, d=10mm, Z_fp=50Ohm)
   b) SAR_1g = 5.2 W/kg (Pin = 100mW, f=2.45 GHz, d=10mm, Z_fp=50Ohm)
   c) SAR_1g = 6.7 W/kg (Pin = 100mW, f=5.8 GHz, d=10mm, Z_fp=50Ohm)
3) In our consulting activities for industry, we have seen many prototype devices violating the spatial peak SAR values for output powers of less than 100mW:

These considerations indicate that devices operating with peak power of less than 100mW have the potential to induce spatial peak SAR values which are by over a factor of

40 above the basic restrictions for partial body exposure. This would also imply that, at a minimum, exclusions are ill advised for devices with an output power above 2mW.

In addition, the rationale provided in Paragraph 18 is misleading because the FCC is assuming based on the submissions that devices under 100mW cannot exceed SAR exposure limits. As we stated above, we have seen many prototypes which exceed the limits even for antenna input power of less than 100mW. The FCC should also be aware that, for example, a spatial peak SAR of 10W/kg in brain tissue will result in a local temperature increase of 1 – 3 degrees (see Attachment [7]).

**Objection No.2: Caution Advised on Spatial Averaging of Incident Fields**

Latest evaluations under plane-wave conditions indicate that current MPE are not consistent with the limits for spatial peak SAR values (see Attachment [6]). In view of this and the lack of data for worst-case considerations for non-uniform incident exposures, spatial averaging is not advisable. Until more data are available, we recommend the use of non-averaged spatial peak SAR values for demonstrating compliance with the spatial peak SAR values. Furthermore, compliance can only be reliably demonstrated in the near-field of the transmitter if *both*, the incident E and H fields, are measured and compared with the MPE limits.

**Objection No.3: Measurements Should Be Required for Compliance Testing (Paragraph: Medical Implant Communications Services)**

In Paragraph 48, is the FCC recommends that compliance can be demonstrated on the basis of FDTD analysis and that this evaluation does not require verification with measurements. FDTD analysis can indeed be reliable *but only if* the device is being correctly simulated. But, there is no way to determine if the analysis is correct. This is especially true given that large simplifications of the transmitter are generally required. Furthermore, studies have shown that FDTD results can be grossly off if those doing the modeling are inexperienced. According to our experience, measurements are much more reliable than computations. Therefore, we strongly recommend that the FCC require that measurements be used for compliance testing. FCC should also consider local temperature increases —these can be substantial (several degrees), even when the spatial peak SAR limits are met. This is already the case for passive devices [4].

**Request: Additional Rationale for Minimum Distances To Qualify for Exemption**

The minimum distances, given in Table 1, for which evaluations are required are not obvious and rationales should be provided. Experts must agree that these distances ensure that both, whole-body and spatial peak SARs, are met under *all* circumstances.

**References**

[1] Niels Kuster and Quirino Balzano, "Energy absorption mechanism by biological bodies in the near field of dipole antennas above 300 MHz", *IEEE Transactions on Vehicular*

*Technology*, vol. 41, no. 1, Feb. 1992, pp. 17–23.

[2] Niels Kuster, Quirino Balzano, and James C. Lin, Eds., "Mobile Communications Safety" Chapman & Hall, London, 1997

[3] IEEE 1528, "Recommended Practice for Determining the Peak Spatial-Average Specific Absorption Rate (SAR) in the Human Head from Wireless Communications Devices: Measurement Techniques," Final Draft, November 2003

[4] Klaus Meier, "Scientific Bases for Dosimetric Assessments in Compliance Tests", PhD Thesis, Diss. ETH Nr.11722, Zurich, 1996.

[5] See Attachment "Frequency Extension to 5 GHz – 6 GHz"

[6] See Attachment "Ratio of Spatial Peak SAR vs. Whole-Body SAR"

[7] See Attachment "ICES SC4 meeting held on June 21, 2003 at Maui, Hawaii"

For the IT'IS Foundation

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# SECOND DRAFT

# Frequency Extension to 5 GHz – 6 GHz

## X.1 Introduction

IEC 62209 Part 1 provides the recommended practice for determining the peak spatial-average specific absorption rate (SAR) in the human head from wireless communications devices for the frequency range 300 MHz – 3 GHz by measurements. The purpose of this Annex is to extend the frequency range for the same applications to 5 - 6 GHz. This Annex only provides the additions and deviations needed for this frequency extension. If nothing is stated here, the requirements, procedures and methods of the main document are applicable.

## X.2 E-field probe and readout electronics

### X.2.1 Special E-field Probe Requirements

The reduced skin depth and reduced size of transmitters at frequencies of up to 6 GHz require smaller probes, which enable measurements closer to the boundary and provide increased spatial resolution. Probes with diameters smaller than 3 mm and sensor center to probe tip offset of less than 1.5 mm are recommended for measurements above 3 GHz. Otherwise the requirements are identical to those below 3 GHz.

### X.2.2 Probe calibration

Due to the strong field decay, transfer calibration based on temperature measurements A.3.2.1 is not recommended for frequencies above 3 GHz. Calculable fields in waveguides generated as described in A3.2.2 are suitable. Guidelines for waveguide systems are given in Table X1

**Table X.1 – Guidelines for designing calibration waveguides**

| | Head Tissue Simulant | | Waveguide Dimension | Penetration Depth | Dielectric Separator | |
|---|---|---|---|---|---|---|
| **Frequency (MHz)** | **□r** | **□ (S/m)** | ***a* (mm)** | **□(mm)** | **□r** | **Thickness (mm)** |
| 4.9– 5.4 | 36.0 | 4.7 | 40.0 | 6.6 | 3.2 | 28 |
| 5.4 – 6.0 | 35.3 | 5.3 | 40.0 | 6.0 | 3.2 | 28[1] |

NOTES_ (1) Permittivity and thickness of the dielectric separator may vary from the values shown to accommodate commercially available materials.

(2) By convention, the length of the cross-section short edge is one-half that of the long edge, i.e., $b = a/2$.

(3) The waveguide dimensions are in accordance with the EIA Standard RS-261-B.

[1] matched by matching screws

## X.3. Phantom models

The requirements for the phantom models defined for the frequencies up to 3 GHz are also applicable for higher frequencies, except that the liquid parameters need to be adjusted (see Table X.2).

**Table X.2 – Target dielectric properties of head tissue-equivalent material in the 3000 MHz to 6000 MHz frequency range**

| Frequency (MHz) | Relative Permittivity (□) | Conductivity (□) (S/m) |
|---|---|---|
| 5000 | 36.2 | 4.4 |
| 5200 | 36.0 | 4.7 |
| 5400 | 35.8 | 4.9 |
| 5800 | 35.3 | 5.3 |

An example of recipe to achieve the above parameters is:

- Water 64%
- Mineral Oil 18%
- Emulsifiers 15%
- Additives and Salt 3%

## X.4. SAR Measurement protocols

### X.4.1 Introduction

The requirements for setup protocol, operational configuration of wireless devices under test, device positions as well as the procedures for SAR evaluations do not deviate from those for the frequency range below 3 GHz. However, adaptation of the scanning methods is required due to the stronger gradients of the field distribution.

### X.4.2 Recommendations for scanning interpolation, and extrapolation methods

*Area Scan:* Due to the reduced penetration depth, the distance between the measured points and phantom surface during area scan need to be reduced as well as the tolerance, i.e., it should be less than 4 mm with a variation of less than ± 0.5 mm during the entire scan. The other requirements remain the same.

*Zoom scan:* The same requirements apply.

*Extrapolation:* The strong decay requires that at least two measurements are taken within the first 5 mm from the liquid-shell interface, preferably at 2 and 4 mm. It is also recommended that the minimal grid spacing do not exceed 2 mm in all directions in order to achieve reliable

extrapolation and interpolation results. In order to keep the overall measurement time within reasonable limits, graded mesh can be used within a Zoom scan.

## X.5. Documenting SAR evaluation

The extended frequency range requires the same documentation including evaluation of the same uncertainty sources. However, the uncertainty analysis needs to be complemented with:

- Due to the small waveguide dimensions, field disturbance by the probe cannot be excluded and must be assessed. Comparison of the area scan with that of a reference probe having a diameter of considerably less than 2 mm may be a suitable technique. The corresponding uncertainty sources are listed in Table X.3
- The minimum penetration depth used to evaluate boundary effect (E.2.3), probe positioner (E.6.2) and probe positioning tolerance with respect to phantom shell surface (E.6.3) is 5 mm.

  The parameter a of the evaluation test functions should be set to 5 mm and function 2 replaced by

$$f_{x2}(x,y,z) = Ae^{-\frac{z}{2a}}\frac{a^2}{a^2+x^2}\left(2-e^{-\frac{z}{a}}\cos^2\left(\frac{\pi}{2}\frac{y}{3a}\right)\right)$$

  The resulting reference values are:

  $SAR_{ref} = (f_1)_{1g} = 0.592$ W/kg, $SAR_{ref} = (f_1)_{10g} = 0.302$ W/kg,

  $SAR_{ref} = (f_{x2})_{1g} = 0.680$ W/kg, $SAR_{ref} = (f_2)_{10g} = 0.236$ W/kg,

  $SAR_{ref} = (f_3)_{1g} = 0.486$ W/kg, $SAR_{ref} = (f_3)_{10g} = 0.091$ W/kg.

**Table X.3 – Uncertainty analysis of the waveguide analytical calibration. Column headings a, b, c are given for reference.**

| | *a* | | *b* | *c* | $u_i = (a/b) \square (c)$ | |
|---|---|---|---|---|---|---|
| **Uncertainty Component** | **Tolerance (± %)** | **Probability Distribution** | **Divisor** | $c_i$ | **Standard Uncertainty (± %)** | $v_i$ |
| | | | | | | |
| Incident or Forward Power | | R | 3 | 1 | | • |
| Reflected Power | | R | 3 | 1 | | • |
| Liquid Conductivity | | R | 3 | 1 | | • |
| Liquid Permittivity | | R | 3 | 1 | | • |
| | | | | | | |
| Field Homogeneity | | R | 3 | 1 | | • |
| Field Disturbance by the Probe | | R | 3 | 1 | | • |
| Field Probe Positioning | | N | 1 | 1 | | • |
| Field Probe Linearity | | R | 3 | 1 | | • |
| | | | | | | |
| **Combined Standard Uncertainty** | | RSS | | | | |

The component tolerances of Table X.3 should be determined as follows:

- The forward power (*Pf*) measurement tolerance should be determined from the power meter and power sensor calibration data.
- The reflected power ($P_r$) tolerance due to mismatch between setup components was measured with a network analyzer. The tolerance is computed as RSS of s11 coefficients of the M&TE used and s11 of the return loss at the liquid/air boundary within the waveguide.
- The liquid conductivity and permittivity tolerances are assessed according to the procedures of E.3.3. Conductivity may be assessed with an improved tolerance by measuring the field decay and permittivity of the tissue-equivalent liquid. This method of assessing conductivity requires the SAR decay and relative permittivity to be measured with high precision; therefore, the permittivity measurement tolerances should be reported when using this method to determine conductivity.
- E-field homogeneity tolerance within the waveguide is evaluated by doing SAR scans throughout the significant liquid volume within the waveguide, at approximately 5 mm from the liquid boundaries, to ensure there are no higher-order modes other than the TE10 mode. Field homogeneity tolerance is determined according to deviations of the measured SAR from a cosine-squared function.
- Field disturbance by the probe is determined by comparison of the area scan with that of a reference probe having a diameter of considerably less than 2 mm.
- E-field probe positioning tolerance is based on the analytical SAR gradient of 30% per mm at 5.8 GHz.
- Field probe linearity uncertainties should be assessed according to the requirements of E.2.4.

## X.6. SAR measurement system verification

The same techniques and methodologies can be applied for system performance check, system validation and interlaboratory comparison guidelines. The corresponding reference dipoles and values are given below. Other methods like open waveguides may also applicable for system performance check.

**Table X.4 – Numerical reference SAR values for reference dipole and flat phantom. All values are normalized to a forward power of 1 W.**

| Frequency (MHz) | 1 g SAR | 10 g SAR | local SAR at surface (above feedpoint) | local SAR at surface (y=2cm offset from feedpoint)[2] |
|---|---|---|---|---|
| 5000 | 77.9 | 22.1 | 305 | |
| 5200 | 76.1 | 21.5 | 309 | 16.3 |
| 5400 | | | | |
| 5800 | 67.6 | 18.9 | 295 | 10.0 |

# Annex X.7

(informative)

## Reference dipoles for use in *system validation*

**Table X.5 – Mechanical dimensions of the reference broad-band dipole (d is the diameter of the dipole arms and dl that of the stub. The phantom shell thickness is 2 mm. The return loss requirements are >15 dB.**

| Frequency (MHz) | *L* (mm) | *h* (mm) | $d_1$ (mm) | $d_2$(mm) |
|---|---|---|---|---|
| | | | | |
| 5000 - 6000 | 20.6 | 40.3 | 3.6 | 2.1 |

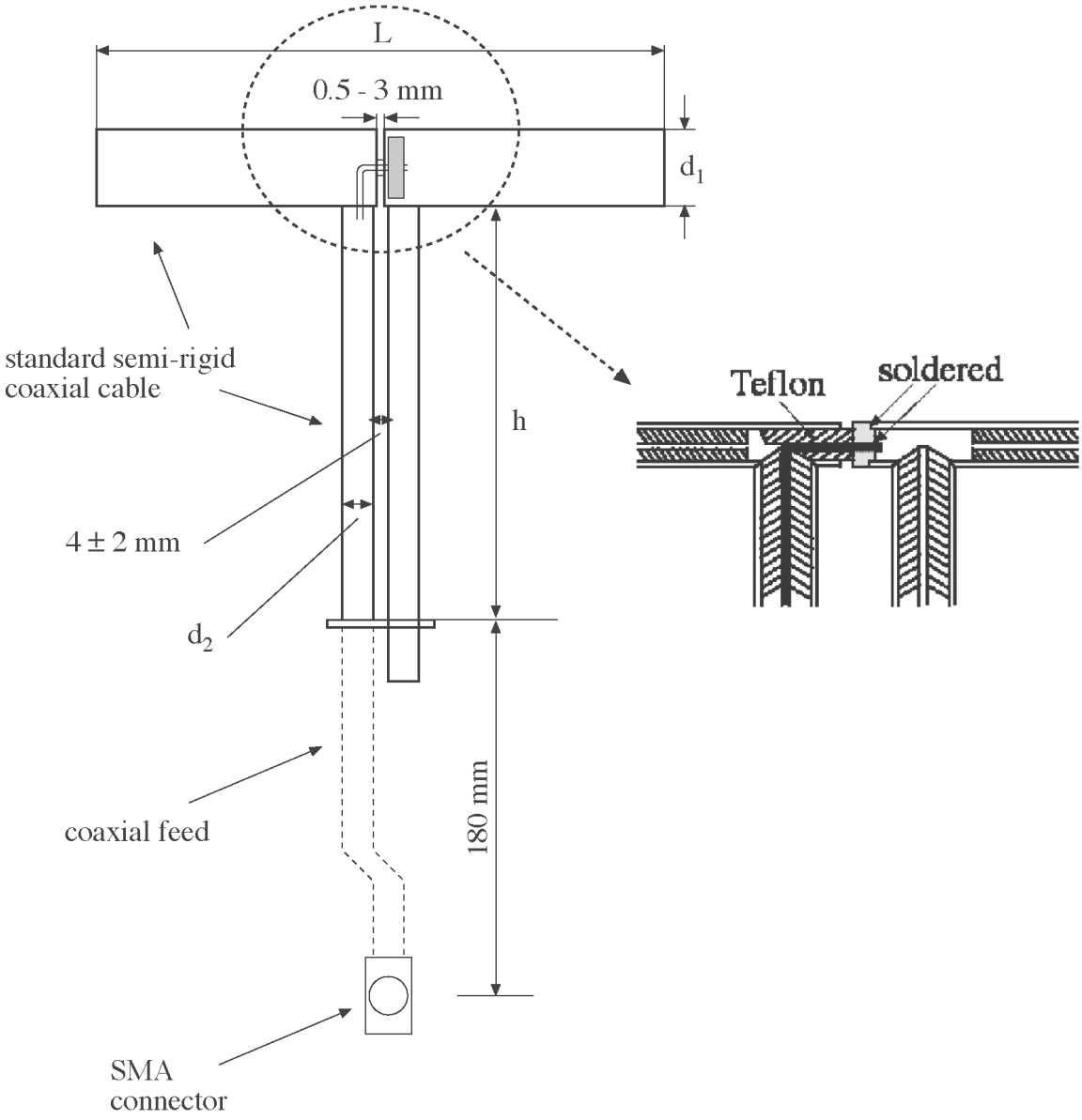


Figure G.1 – Reference

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# Ratio of Spatial Peak SAR vs. Whole-Body SAR

December 6, 2003

## 1 Introduction

In order to review the basis of the current safety guidelines preliminary simulations were carried out. The quantities of interest are the ratio of the spatial peak SAR vs. whole-body SAR In the current standard, a ratio of 20 is assumed to be sufficient which is based on numerical simulations using approximate models of humans. Nowadays whole-body human models such as the "Visual Human Project" data set are available enabling the accurate assessment of electromagnetic quantities of interest.

## 2 Method & Results

All numerical simulations were carried out with SEMCAD V1.6. The whole-body human phantom based on the "Visual Human Project" data set was irradiated by a plane wave. The incident direction was either frontal or lateral. The whole-body human phantom was not grounded in all simulations. In all scenarios considered, the spatial peak SAR over 10 g and 1 g were evaluated according to the the IEEE C95.1 standard and IEEE 1529 draft. The maximum values for the ratio of the spatial peak SAR (1g averaged) vs. the whole-body SAR are given in Table 1.

| $Frequency$ $[MHz]$ | Ratio Spatial $\text{Peak}_{1g}$ vs. WB |
|---|---|
| 450 | 35 |
| 900 | 45 |
| 1 800 | 41 |
| 2 450 | ?? |
| 5 800 | ?? |

Table 1: Computed ratio of spatial peak SAR averaged over 1 g vs. whole-body SAR (WB)

## 3 Conclusions

The ratio of spatial peak SAR averaged over 1 g vs. whole-body SAR is clearly larger than the implied factor of 20 in the current standard. This is even true for the chosen human model which is not representative nor worst-case with respect to absorption at these higher frequencies. This implies that the limits of the spatial peak SAR may be significantly violated, even though the incident field is below the MPE limits. This contradicts the basics of the MPE. The non-compliance with the spatial peak SAR might be even more severe in case of non-uniform exposure situations. In other words, the current MPE are not consist with the basic limits. Further investigations are needed to develop a revised set of MPE. In the next months, we will devote some of our resources in addressing this issue.

Draft September 22, 2003

ICES SC4 meeting held on June 21, 2003 at Maui, Hawaii

Action item

| | | | |
|---|---|---|---|
| 19. | Review supporting material that led to the revised NRPB peak spatial-average SAR value and provide a conclusion regarding its validity. | Elder, Chou, Kuster, Tofani | August 31 |

We held three telephone conferences on July 16, 24, and 31, 2003. In addition to the four SC4 members, one additional expert recommended by Niels Kuster contributed to the discussion.

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**1. Santi Tofani presented the problem:**

In the comments below, two concerns were summarized by SC4 member Santi Tofani about temperature rises in the eye and in the brain.

*Comments by S. Tofani on PARTIAL BODY EXPOSURE LIMITS for the Maui SC4 Meeting, June 21, 2003*

*1- Present IEEE Standard for partial body exposure:*

*8 W/kg over 1 g with no biological rationale.*

*2- Present ICNIRP-WHO (1998) Standard:*

*10 W/kg over 10 g with the biological rationale intended to avoid any local temperature elevation above 1 °C (with particular attention to the eye, considered the most sensitive organ to temperature increase).*

*Problems with the ICNIRP standard:*
*- Eye: 10 W/kg averaged over the eye may lead to a temperature rise, in the region of the lens, well above 1 °C (see papers sent by Tofani to SC4 and reported as attachment 6 of file ICES SC4 Meeting Minutes-December 2002.doc mailed by SC4 Co-Chairman on Feb. 10, 2003) and estimated up to 4 °C by*

*NRPB (see NRPB 1 May 2003 document at p. 114 § 571). Baseline lens temperature is 36 °C.*
*- Brain: 10 W/Kg averaged in 10 g is correlated, by NRPB, with an highest calculated value of brain temperature increase of 1.6 °C (see NRPB 1 May 2003 document at p. 92 § 435, 436 and p. 114 § 570, 572; referring to the papers of Wainwright (2000) and Van Leeuwen et al. (1999)). Baseline temperature is 37 °C.*

*3- The NRPB biological rationale for partial body exposure is to limit the rise in temperature of the head and spinal cord to 38 °C, other tissues of the neck and trunk (with the exception of the testes) to 39 °C, and limbs to 40 °C. The testes should not be exposed to a temperature increase above 1 °C.*

*4-In both cases, adoption of the ICNIRP biological rationale (1°C) or the NRPB rationale (38 °C) leads to a local SAR limit for the head of 5 W/kg over 10 g of averaging mass according to the precautionary approach based on the highest calculated/measured temperature values. The 5 W/kg over 10 g is very similar to the present IEEE value of 8 W/kg over 1 g; data supporting this conclusion may be found in many papers, e.g., see the two papers cited above by Wainwright and Van Leeuwen.*

**2. NRPB raised the concerns**

In the NRPB Consultation Document, paragraphs 435, 571 and 572 discuss a possible rationale for proposing to lower the occupational partial-body SAR limit from 10 W/kg per 10 g of tissue to 5 W/kg per 10 g. These paragraphs present the following arguments, aimed at limiting temperature rise in the brain and the eye:

a) Paragraph 571: “Studies of heating in the eye suggest that an SAR of 1 W/kg averaged over the eye, may lead to a temperature rise of 0.4 oC in the region of the lens.”

b) Paragraph 435:, “The maximum temperature rise in the brain was predicted to be 0.4 $^{o}$C for 1800 MHz and 0.2 $^{o}$C for 900 MHz, for a 1 W antenna. The corresponding peak 10 g averaged SAR values are 2.43 W/kg and 1.43 W/kg, respectively.” Page 114, Paragraph 570: “The results indicate a range of localized temperature increase of 0.05 to 0.16 $^{o}$C in the brain for a localized SAR of 1 W/kg. The highest of this range is from an NRPB study and indicate that, in order to limit the temperature in all parts of the brain to 38 oC (corresponding to a temperature rise of 1 oC above baseline) the SAR in the head, averaged over 10 g, should not exceed about 6 W/kg.”

c) Paragraph 572: “The above proposals for restricting localized temperature increases in the body associated with partial-body exposure indicate the need to

consider a reduction in the occupational basic restriction for localized SAR for the head and truck. Adopting a precautionary approach based on the highest calculated value of temperature increase in the brain associated with SAR (0.16 $^{o}$C corresponding to 1 W/kg) and calculations on possible temperature rise in the eye, indicates the need to restrict localized SAR to about 5 W/kg averaged over 10 g mass. Given the uncertainties indicated by the range of published dosimetric data relating temperature rises with localized SAR, NRPB proposes that further dosimetric studies addressing this topic should be carried out."

**2.1 Temperature rise in the eyes**

The references used by NRPB for the eye.

a) Hirata A, Ushio G and Shiozawa T (1999). Formation of hot spots in the human eye for plane wave exposures. Proc. 1999 Asia Pacific Microwave Conference, Singapore, 477-80.
b) Hirata A, Matsuyama S and Shiozawa T (2000). Temperature rises in the human eye exposed to EM waves in the frequency range 0.6 – 6 GHz. IEEE Trans Electromagnetic Compatibility, 42, 386-92.

Both theoretical papers are from Akimasa Hirata and associates of Japan. The 1999 conference proceeding paper reported that 1 mW/cm$^2$ (0.36 W/kg) could induce 0.14-$^{o}$C rise in eye. This result is quoted "Studies of heating in the eye suggest that an SAR of 1 W/kg averaged over the eye, may lead to a temperature rise of 0.4 $^{o}$C in the region of the lens" (p. 96). Based on this result, at 10 W/kg, the temperature rise in the eye would be 4 $^{o}$C. This study was based on an analysis of an isolated eyeball model without the presence of the head. As a result, this is an inappropriate model for numerical calculations intended for the consideration of human exposure limits. The authors recognized the simplicity of their first model and made corrections in their subsequent studies to include the head. Using the data reported in Hirata et al. (2000), Table 1 lists the maximum temperature increases in the eye exposed to 1, 1.9 and 6 GHz. Assuming a linear relationship between SAR and temperature rise, the maximum temperature rise in the lens exposed to 2 and 10 W/kg for the three frequencies are calculated, as shown in the following table.

Table 1 Maximum eye temperature rises due to exposure to 1, 1.9 and 6 GHz

| Frequency (GHz) | 2 W/kg (10 g) limit | 10 W/kg (10 g) limit |
|---|---|---|
| 1 | 0.217 (humor) | 1.09 |
| 1.9 | 0.241 (humor) | 1.21 |
| 6 | 0.445 (cornea) | 2.22 |

Examining the model used by Hirata et al. in their earlier 2000 paper and in their more recent paper in 2002, we note that the only thermal transfer was through heat conduction and eye surface cooling because blood flow was neglected.

Neglecting blood flow leads to overestimates of the maximum temperature rise listed in Table 1 for the following reasons:

a) The statement that the eye cannot effectively dissipate heat due to limited blood vascular systems is frequently mentioned, but Carpenter et al. (1977) took exception to this statement based on the following simple experiment. “If the temperature at the posterior pole of the lens in an anesthetized rabbit is measured prior to and during microwave irradiation, it may be found to rise perhaps 5 $^{o}$C in the course of a 15-minute exposure. If a lethal dose of anesthetic is then injected intravenously, the heart will stop beating, whereupon the intraocular temperature will rapidly rise another 10 $^{o}$C, thus indicating that the vascular system is capable of handling at least two-thirds of the thermal stress which radiation imposes on the eye” (Carpenter et al., 1977, p. 354).

b) In the thermal analysis paper by Emery et al. (1975), the eye blood flow rate (5% iris, 22% ciliary and 72% choroids, sclera and retina) had to be set at 1.7 cm$^3$/min at 100 mW/cm$^2$, 2.7 cm3/min at 200 mW/cm$^2$ and 4 cm$^3$/min at 300 mW/cm$^2$ in order to match the experimental measurement of temperature rise in anesthetized rabbit eyes. Without the blood flow included, the calculated temperature rises were much higher than the measured values.

c) In rabbits, Kojima et al. (2002) reported “intraocular temperatures were significantly higher in the group with general anesthesia than in the group without anesthesia.” Based on the above three animal studies (dead vs anesthetized rabbit, thermal modeling compared with experimental data, anesthetized vs unanesthetized rabbits), the model used by Hirata et al. without blood flow (i.e., dead human) overestimates the temperature rise in a human eye by at least 3 times as compared to that in unanesthetized humans. At the 10 W/kg (10 g) limit, the maximum temperature rise in the human eye should be below 1 $^{o}$C. The current ICNIRP occupational peak SAR limit is adequate for human eye protection.

**Conclusion: The temperature rise in the eye based on modeling studies represents worst case data because the influence of physiological blood flow has not been taken into account.**

References for the eye issue are:

1. Hirata A, Watanabe H and Shiozawa T (2002). SAR and Temperature Increase in the Human Eye Induced by Obliquely Incident Plane Waves. IEEE Trans Electromagnetic Compatibility, 44, 592-594.
2. Carpenter, R.L., G.J. Hagan and G.L. Donovan (1977). Are microwave cataracts thermally caused? In: Symposium on Biological Effects and Measurement of Radio Frequency/Microwaves, D.G. Hazzard, editor, HEW Publication (FDA) 77-8026, Rockville, MD, pp. 352-379.

3. Emery AF, Kramar P, Guy AW, and Lin JC (1975): Microwave induced temperature rises in rabbit eyes in cataract research. Journal of Heat Transfer, Transactions of ASME. February 1975, pp. 123- 128.
4. Masami Kojima, Ikuho Hata, Kanako Wake, Soichi Watanabe, Kazuyuki Sasaki, Masao Taki, Yoshitsugu Kamimura, Yukio Yamanaka (2002): The Effect of General Anesthesia on the Threshold Decision of Ocular Side Effects Induced by Microwave Radiation in Rabbit Eyes, URSI XXVIIth General Assembly, Maastricht, the Netherlands. August 17-24, 2002.

**After agreeing that the concern for temperature rise in the eye can be explained by the lack of blood flow, we moved on to the brain temperature issue.**

### 2.2 Temperature in the brain

For the brain, the following papers were cited by NRPB:

1. Bernardi P, Cavagnaro M, Pisa S and Piuzzi E (2000). Specific Absorption Rate and Temperature Increases in the Head of a Cellular-Phone User. IEEE Trans on Microwave Theory and Techniques, 48, 1118-1126.
2. Gandhi O, Li Q and Kang G (2001). Temperature Rise for the Human Head for Cellular Telephones and for Peak SARs Prescribed in Safety Guidelines. IEEE Trans on Microwave Theory and Techniques, 49, 1607-1613.
3. Van Leeuwen G M J, Lagendijk J J W, Van Leersum B J A M, Zwamborn A P M, Hornsleth S N and Kotte A N T J (1999). Calculation of change in brain temperatures due to exposure to a mobile phone. Phys. Med. Biol. 44 (1999), 2367- 2378.
4. Wainwright P (2000). Thermal effects of radiation from cellular telephones. Phys. Med. Biol. 45 (2000), 2363-2372.
5. Wang J and Fujiwara O (1999). FDTD Computation of Temperature Rise in the Human Head for Portable Telephones. IEEE Trans on Microwave Theory and Techniques, 47, 1528-1534.

Wainwright (2000) of NRPB reported that the highest calculated value of brain temperature increase was 1.6 $^{o}$C when exposed to 10 W/kg averaged over 10 g tissue; an increase of 1.2 $^{o}$C was reported by van Leeuwen et al. (1999). Information in the Wainwright paper is confusing. Although the maximum calculated temperature increase was 1.6 $^{o}$C, Wainwright stated that "More extensive examination of the temperature profile shows that at no point does the absolute temperature in the brain exceed 38.1 $^{o}$C in any of the cases considered" and in the conclusion he states "It [the model] has also been applied to investigate the effects of a realistic exposure profile at the ICNIRP occupational exposure limit of 10 W/kg. This indicates that such exposure is unlikely to cause the temperature in the brain to rise by more than about 1 $^{o}$C above the normal body core temperature." In addition, Gandhi et al. (2001) and Wang and Fujiwara (1999) showed 0.5 to 0.6 $^{o}$C increase with the same exposure. No comparison is made to the results in Bernardi et al. (2000) because this paper provided

temperature data only for SARs averaged over 1 g. In the absence of experimental data validating the calculations in the above five papers, the modeling results must be considered worst-case data. Furthermore, the physiological relevance of the modeling studies is not known.

As stated in Paragraph 572, the NRPB recognized some of the uncertainties indicated by the range of the modeling data relating temperature rise with localized SAR. Our analysis identified additional uncertainties and because of these uncertainties we agree with NRPB that more dosimetry research is needed to determine the validity of the modeling. We encourage the development of a collaborative process to determine how that is best pursued.

In addition to the papers cited in the NRPB document, we found 4 other papers related to this subject.

[1] Paolo Bernardi, Marta Cavagnaro, Stefano Pisa and Emanuele Piuzzi. "Power Absorption and Temperature Elevations Induced in the Human Head by a Dual-Band Monopole-Helix Antenna Phone", IEEE Transactions on Microwave Theory and Techniques, vol. 49, no. 12, pp. 2539-2546, December 2001.
[2] T. V. Yioultsis, T. I. Kosmanis, E. P. Kosmidou, T. T. Zygiridis, N. V. Kantartzis, T. D. Xenos, and T. D. Tsiboukis (2002). A Comparative Study of the Biological Effects of Various Mobile Phone and Wireless LAN Antennas. IEEE TRANSACTIONS ON MAGNETICS, 38(2): 777-780.
[3] Akimasa Hirata, Masashi Morita and Toshiyuki Shiozawa. "Temperature Increase in the Human Head Due to a Dipole Antenna at Microwave Frequencies", IEEE Transactions on Electromagnetic Compatibility, vol. 45, no. 1, pp. 109-116, February 2003.
[4] Akimasa Hirata and Toshiyuki Shiozawa. "Correlation of Maximum Temperature Increase and Peak SAR in the Human Head due to Handset Antennas", IEEE Transactions on Microwave Theory and Techniques, vol. 51, no. 7, pp. 1834-1841, July 2003.


Temperature rise i
head of mobile pho

The attached Excel file summarized the analysis of 9 papers. When the peak SAR is 10 W/kg averaged over 10 g head tissue, four papers show that the brain temperature increase is greater than 1 $^{o}$C (van Leeuween et al. [1999], Bernardi et al. [2000], Wainwright [2000] and Yioultsis et al. [2002]). In their more recent paper, Bernardi et al. [2001] showed the temperature change was lower, that is, the change was just over half of their 2000 results. The highest temperature rise of 1.64$^{o}$C is reported by Wainwright [2000]. His response to our inquiry (shown below) revealed that his re-examination of his study showed that the value of 1.64 is too high and that this value was found outside the skull.

Dear Peter:

Recently we responded to the NRPB proposed document. During the process, we studied your paper:

Peter Wainwright. "Thermal effects of radiation from cellular telephones", Physics in Medicine and Biology, vol. 45, pp. 2363-2372, 2000.

I have some questions on the paper and need your help to clarify:

On page 2371, first paragraph under Figure 4, "...., the maximum temperature rise in the brain can be deduced from table 4 by multiplying the ratio in the last column by 10. At that level the temperature rise is no greater than 1.6oC. More extensive examination of he temperature profile shows that tat no point does the absolute temperature in the brain exceed 38.1 oC in any of the cases considered".

1. From Table 4, LATh 1800 MHz, the temperature rise 0.164 x 10 = 1.64 $^{o}$C. Why is this no greater than 1.6$^{o}$C?

**ANSWER: This is simply a difference in rounding. More than two significant figures was felt to suggest a spurious level of precision.**

2. I cannot see how the next sentence is connected to it. On page 2367, the brain temperature is 37.3 oC. Then 37.3 + 1.64 = 38.94 > 38.1.

Then in the conclusion, "It has also been applied to investigate the effects of a realistic exposure profile at the ICNIRP occupational exposure limit of 10 W/kg. This study seems to confirm that such exposure is unlikely to cause the temperature rise in the brain to rise by more than about 1 oC above the normal body core temperature."

**ANSWER:**
**Recent re-examination of the data and the anatomical phantom used for the calculations suggests that the 1.64 figure is indeed too high. Artefacts in the original (MRI-derived) model led to a situation whereby a few elements of muscle tissue were mis-identified as brain.**

**The highest values of brain temperature rise, per (W/kg), for the CONTROL case using the "normal" blood flow values are now thought to be**

**0.112 (LATh@1800), 0.122 (LATh@900), 0.109 (LATv@1800), 0.105(LATv@900).**

**However, sensitivity of the results to blood perfusion rate is greater than thought before. Assuming the perfusion rate in brain to be HALF its control value, the temperature rise for LATh@1800 then becomes 0.145.**

**In retrospect, the apparent discrepancy between 1.6 temperature RISE and 38.1 ABSOLUTE temperature becomes clear. The point where this 1.6 maximum occurs was actually found to be in the muscle OUTSIDE the skull where the baseline temperature was 36.5oC.**

**Note that the baseline temperature in this model is not uniform even within the brain; there is a temperature gradient on the periphery. The outermost regions of the brain start at about 36.9oC in this model. Therefore at the ICNIRP SAR value we have the absolute temperature 36.9+10*0.122 = 38.1.**

**These points will, of course, be taken into consideration as we prepare the next draft of the guidelines document.**

**Yours sincerely,**
**Peter R Wainwright.**

I must have missed something, please explain how the 1.6 $^{o}$C rise become less than 0.7 $^{o}$C. This is a very important conclusion because as you know NRPB document is proposing a lowering of the 10 W/kg to lower limit based on your 1.6 degree rise data. We must have a solid scientific rationale to make a change.

Thank you in advance for your reply.

C.K. Chou, Ph.D.


BrainSAR.doc

Santi also questioned the averaging volume (see attached).

Responses to our inquires to Gandhi, Bernardi and Hirata about the shape of their averaging volume revealed that Benardi and Hirata used a cubic averaging volume. [Need to check with Yioultsis et al.]

Conclusion: The results of 9 modeling papers on this subject lack consistency. The adequacy of physiological blood flow in the numerical model studies is unclear. Furthermore, none of the results have been verified in a live animal. Whether these studies are applicable for the development of human exposure limits will be discussed in the meeting.